## Remarks

### *I. Status of the Claims*

Claims 1-14 remain pending under examination in this application. No claims have been added in this response. Applicants have amended Claims 1-4 herein to further clarify the subject matter being claimed. Enabling support for the amendments can be found in the application as filed (*See, e.g.*, page 8, lines 7-9, page 8, lines 20-24, and page 9, lines 16-17). Therefore, no new subject matter was introduced by the claim amendments. Reconsideration of the present application and allowance of Claims 1-14 are respectfully requested in view of the following remarks.

### *II. Claim Rejections under 35 U.S.C. § 112, second paragraph*

The Office Action rejected Claims 1-14 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action asserts that the expression "disease-associated activatory processes" used in Claim 1 is vague and indefinite and allegedly leaves one of ordinary skill in the art in doubt as to the meaning of the technical features to which it refers, thereby rendering the metes and bounds of the claim unclear. Applicants respectfully submit that Claim 1, as previously presented, was not vague or indefinite, and would be clear to one of ordinary skill in the art as to the meaning of the technical features to which it refers. Specifically, the specification clearly states that a "preferred function for caspase-10 within the scope of the present invention is the activation of cytokinsecretion, either indirectly via intermediary signaling pathways or by direct proteolytic maturation." (See, page 5, lines 7-9) Further, page 5, lines 20-24 and page 9, lines 16-17 disclose further functions of caspase-10 as induction of direct cell bound signals and as a transmitter of signals regulating proliferation, differentiation, and/or senescence. Applicants respectfully submit that one skilled in the art would readily appreciate that disease-associated activatory processes would include the activation of cytokinsecretion, induction of direct cell bound signals, or transmission of signals regulating proliferation, differentiation, and/or senescence. Regardless, to further the prosecution of the pending claims, Applicants have amended Claim 1 to specifically recite these processes as

those included as "disease-associated activatory processes." Applicants have also amended Claims 1-4 to change the term "processes" to "process" to more clearly describe the claimed subject matter. No new matter is added by these amendments and Applicant's respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection.

### *III. Claim Rejections under 35 U.S.C. § 102(b)*

The Office Action rejected Claims 1-14 under 35 U.S.C. § 102(b) as allegedly being anticipated by Alnemri (U.S. 5,786,173). Specifically, the Office Action alleges that Alnemri discloses methods of monitoring and modulating disease-associated activatory processes comprising determining and/or influencing the amount or activity of Mch4 (which is the caspase 10a isoform) in a cell or organism at the nucleic acid level and protein level. The Office Action further alleges that although it is not further specified that non-apoptosis signals are meant, cancer and autoimmune diseases are included for treatment and monitoring, and these types of diseases fall under the group of activatory processes that are also triggered by non-apoptosis signals.

Applicants respectfully submit that Alnemri does not anticipate the claims as amended. Specifically, there is no literal or inherent teaching by Alnemri that a disease associated process such as activation of cytokinsecretion, induction of direct cell-bound signals, or transmission of signals regulating proliferation, differentiation, and/or senescence can be monitored and modulated by determining and influencing the amount or activity of caspase-10 or caspase-10 isoforms. Alnemri, therefore, does not teach or suggest monitoring and modulating a specific activatory process, such as activation of cytokinsecretion, induction of direct cell-bound signals, or transmission of signals regulating proliferation, differentiation, and/or senescence, by performing the step of determining and influencing the amount of caspase-10 or caspase-10 isoforms in a cell.

Further, Alnemri neither literally or inherently discloses that the activatory process is triggered by non-apoptosis signals emanating from death receptors or non-apoptosis signals emanating from non-death receptor members of the TNF receptor family. The Office Action

alleges that because some of the diseases listed in Alnemri fall under the group of activarory processes that are also triggered by non-apoptosis signals and inherently include the death receptors and non-death receptors claimed by Applicant as well as receptor crosslinking. Applicants respectfully traverse this rejection.

Specifically, the Office Action alleges that Alnemri discloses cancer and autoimmune diseases are included for treatment and monitoring and the present application includes these diseases. Applicants respectfully assert the list of diseases in the present application is a list of diseases that may be selected as one of those having a disease-associated activatory process. Therefore, simply because there may be some general overlap in the diseases listed in Alnemri and that within the present application, this is insufficient to then assume Alnemri inherently anticipates the presently claimed invention by assuming all the diseases listed in Alnemri inherently are triggered by non-apoptosis signals emanating from death receptors or non-apoptosis signals emanating from non-death receptors of the TNF receptor family.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *See, In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art) and *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. *The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*") (emphasis added). Here, the Office Action admits that Alnemri does not disclose non-apoptosis signals and that only two general types of diseases disclosed in Alnemri fall within the group of activatory processes that may also be triggered by non-apoptosis signals. The Office Action then alleges these diseases inherently include death receptors and non-death receptors claimed by Applicant as well as receptor crosslinking. Applicants respectfully assert that *In re Robertson* is particularly relevant to this rejection because the rejection is based on an assumption that these processes are inherently disclosed by Alnemri,

whereas Alnemri neither literally nor inherently disclose these processes. Applicants respectfully assert, consistent with *In re Robertson,* that if one or more of the disease-associated activatory processes *might* be present in the diseases disclosed by Alnemri, this is insufficient for a rejection based on anticipation. The mere assumption that the diseases listed in Alnemri inherently include the claimed disease associated activatory processes as those disclosed by the present invention is speculative and insufficient to support an anticipation rejection. Therefore, Applicants respectfully request withdrawal of this 35 U.S.C. § 102(b) rejection and request allowance of the pending claims.

The foregoing is submitted as a full and complete response to the Office Action mailed November 15, 2007. If there are any issues which can be resolved by telephone conference, the Examiner is invited to call the undersigned attorney at (404) 853-8081. No additional fees are believed to be due, however, the Commissioner is hereby authorized to charge any additional fees due or credit any overpayment to Deposit Account No. 19-5029.

Respectfully submitted,

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